

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Tuesday, September 04, 2007

MEMORANDUM

Subject:

Acute Toxicity Review for EPA Reg. No.: 59894-10/

Kwikkill Disinfectant Deodorizing Wipes

DP Barcode: D337816

To:

Marshall Swindell, PM 33

Regulatory Management Branch

Antimicrobials Division (7510C)

From:

Ian Blackwell, Biologist

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510C)

Through:

Karen Hicks, Team Leader

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510C)

Michele E. Wingfield, Chief Product Science Branch

Antimicrobials Division (7510C)

Applicant:

M&S Research

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
N-Alkyl dimethyl benzyl ammonium chloride	0.12
N-Alkyl dimethyl ethyl benzyl ammonium chloride	0.12
Isopropyl alcohol	41.58
Other Ingredient(s):	58.18
Total:	100.00

1) <u>BACKGROUND</u>: M&S Research has submitted a primary eye irritation study to support their product, "Kwikkill". No other studies, reports or citations were included in this submission. The study was conducted by Product Safety Laboratories.

CTT has not been able to locate any prior acute toxicity reviews of this product.

2) RECOMMENDATIONS: PSB findings are:

- a) The primary eye irritation study is acceptable.
- b) The Chemistry and Toxicology Team (CTT) is not able to locate any prior acute toxicity reviews for this product. Thus, the acute toxicity profile for 59894-10 will be incomplete.

The acute toxicity profile for Registration Number 59894-10 is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity			Data Gap
Acute Dermal Toxicity			Data Gap
Acute Inhalation Toxicity			Data Gap
Primary Eye Irritation	470130-01	II	Acceptable
Primary Skin Irritation			Data Gap
Dermal Sensitization			Data Gap

3) LABELING:

- a) Due to a lack of acute toxicity data for this product, the precautionary labeling recommendations will be limited.
- b) The signal word will be at least Warning, based upon the results of the primary eye irritation study. If the results of one of more other studies supporting this study are toxicity category I, the signal word must be elevated to Danger.
- c) The Precautionary Statements should include:

"Causes substantial, but temporary, eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Wash thoroughly with soap

and water after handling and before eating, drinking, chewing gum, using tobacco, or, using a restroom. Remove and wash contaminated clothing before reuse."

Due to a lack of acute toxicity data for this product, CTT cannot state whether additional precautionary statements are required for this product.

d) The First Aid statements must include:

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing.
- · Call a Poison Control Center for treatment advice.

Again, due to an absence of a complete acute toxicity profile, CTT cannot state whether other First Aid statements are required for this product.

e) The registrant might consider language that specifically warns the user not to rub his or her eyes after using the product without first washing his or her hands.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 33

Reviewer:

I. Blackwell

MRID No.:

470130-01

Study Completion Date: 1/14/2005

Lab Study No.:

16457

Testing Laboratory: Product Safety Laboratories

Author(s): Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): Included

Test Material: Kwikkill Disinfectant, Cleaning & Deodorizing Solution

Dosage: 0.1 mL

Species: New Zealand White rabbit

Sex: 1 male + 2 females

Weight: Not reported

Source: Robinson Services, Inc.

Age: Young adult

Summary:

1. Toxicity Category: II

2. Classification: Acceptable

Procedure (Deviations From §81-4):

Results:

	(number "positive"/number tested)								
Observations	Hour	Days							
	1	1	2	3	4	7	10	14	
Corneal Opacity	3/3	3/3	3/3	3/3	2/3	1/3	0/3		
Iritis									
Conjunctivae									
Redness	3/3	3/3	3/3	3/3	0/3	0/3	0/3		
Chemosis	0/3	2/3	1/3	0/3	0/3	0/3	0/3		
Discharge	3/3	3/3	3/3	3/3	0/3	0/3	0/3		

^{- - - =} no observations at this point